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FX miniRAIL™

RX Percutaneous Transluminal Coronary Angioplasty Catheter (PTCA)

Instructions for Use

NOTE: These instructions pertain to all available balloon lengths and diameters.

CAUTION

Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

STERILE

Sterilized with ethylene oxide gas. **Do not use if the package is open or damaged.**

DESCRIPTION

The FX miniRAIL™ balloon angioplasty catheter is a rapid exchange, PTCA catheter that features a dual wire platform. This 6F compatible system creates controlled plaque fractures with longitudinal expansion planes at low inflation pressures.

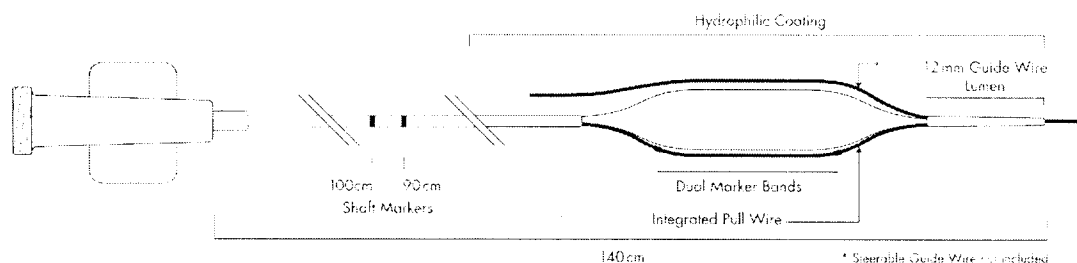
The balloon is connected to the distal tip which provides a short guide wire lumen. The proximal end of the balloon is connected to an inflation channel, which floats freely inside the catheter shaft. The integrated pull wire connects the shaft to the distal tip.

Two radiopaque markers are mounted on the pull wire delineating the working segment of the balloon. This facilitates fluoroscopic visualization of the balloon during use.

The FX miniRAIL™ semi-compliant balloon material is designed to expand to a specified diameter and length at a specified pressure. The hydrophilic coating of the balloon requires that the catheter be wetted to achieve its properties. The following table outlines the available models.

MODEL NUMBERS for FX miniRAIL™ Catheters – 10, 15, 20 & 30mm Lengths					
Model *	FX20XX	FX25XX	FX30XX	FX35XX	FX40XX
Balloon Diameter	2.0 mm	2.5 mm	3.0 mm	3.5 mm	4.0 mm

* XX indicates length, e.g., FX2010 Balloon = 2.0 mm diameter and 10.0 mm length



CONTENTS

One (1) FX miniRAIL™ RX PTCA Catheter

STORAGE

Store in a dry, dark, cool place.

INDICATIONS

The FX miniRAIL™ RX PTCA Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery, including in-stent restenosis, for the purpose of improving myocardial perfusion.

CONTRAINDICATIONS

Unprotected left main coronary artery

Coronary artery spasm in the absence of a significant stenosis

WARNINGS

This device is intended for single (one) use only. Do not resterilize and/or reuse it, as this can potentially result in compromised device performance and increased risk of inappropriate resterilization and cross contamination.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery require careful consideration, including possible hemodynamic support during PTCA, as treatment of this patient population carries special risk.

When the catheter is exposed to the vascular system, it should be manipulated while under high quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met

during manipulation, determine the cause of the resistance before proceeding.

Balloon pressure should not exceed the rated burst pressure (RBP). [The RBP is based on results of in-vitro testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their RBP. Use of a pressure monitoring device is recommended to prevent over-pressurization.]

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team must be on alert when a PTCA procedure is being performed.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

The FX miniRAIL™ Catheter is not intended for stent deployment.

Use the catheter prior to the "Use Before" (expiration) date specified on the package.

PRECAUTIONS

If the surface of the FX miniRAIL™ Catheter becomes dry, wet the catheter with heparinized normal saline.

Do not reinsert the FX miniRAIL™ Catheter into the packaging hoop after procedural use.

Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.

Only physicians trained in the performance of percutaneous transluminal coronary angioplasty should use the catheter system.

During the procedure, appropriate anticoagulant and coronary vasodilator therapy must be provided to the patient as needed. Anticoagulant therapy should be continued for a period of time to be determined by the physician after the procedure.

Do not rotate the catheter shaft in excess of 180 degrees when the tip is constrained.

Catheter manipulation, including advancement and retraction, should be performed by grasping the black hypotube shaft.

Do not rotate the catheter luer hub in excess of five (5) turns during use. If the inflation lumen becomes stretched and the tubing becomes exposed at the end of the silver strain relief, the catheter's performance may be compromised. Discontinue use and replace catheter.

Guide wire prolapse may occur as the FX miniRAIL™ catheter is withdrawn. Do not advance or retract the FX miniRAIL™ catheter over the floppy portion of the guide wire. If guide wire prolapse occurs, attempt to resolve the prolapse by gently pulling back on the

guide wire under fluoroscopic control until the guide wire becomes coaxial with the FX miniRAIL™ catheter.

If unusual resistance is felt when the catheter is being manipulated OR if it is suspected that the guide wire has become kinked, remove the entire catheter system (FX miniRAIL™ and steerable guide wire) as a unit.

If fluoroscopic guidance indicates that the FX miniRAIL™ catheter has advanced beyond the end of the guide wire, withdraw the catheter and reload the wire before advancing again.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to the following:

- Death
- Acute myocardial infarction
- Total occlusion of the coronary artery
- Coronary vessel dissection, perforation, rupture, or injury
- Hemorrhage or hematoma
- Unstable angina
- Arrhythmias, including ventricular fibrillation, or other conduction disturbances
- Drug reactions, allergic reaction to contrast medium
- Hypo/hypertension
- Infection
- Coronary artery spasm
- Arteriovenous fistula
- Embolism
- Thrombosis

SUMMARY OF CLINICAL STUDIES

A multi-center, non-randomized, single-arm prospective clinical trial was conducted to evaluate the safety and effectiveness of the FX miniRAIL™ catheter in patients with single or multiple vessel coronary artery disease who were scheduled to undergo percutaneous coronary intervention because of symptoms of stable or unstable angina pectoris. Twelve sites entered a total of 263 patients eligible for elective coronary angioplasty who met the inclusion/exclusion criteria.

The primary endpoints for the study were procedural success and clinical success. Procedural success was defined as angiographic success without death, Q-wave or non-Q wave MI, or emergency CABG during hospital stay. Angiographic success was defined as < 50% final diameter stenosis in at least one of the FX-attempted lesions. Clinical success rate was defined as freedom from MACE, defined as death, any MI (Q-wave or non Q-wave), or CABG at 14-day follow-up. Coronary angiography, consistent with QCA standards, was performed before and immediately after angioplasty with the FX miniRAIL™ catheter. Stenosis resolution was measured by on-line QCA. The initial, post-FX, and final lesion status were assessed both by on-line and off-line QCA, measuring percentage of diameter stenosis, percentage of area stenosis, post-FX minimal luminal diameter, and mean reference diameter. All major adverse clinical events were source documented and adjudicated by an independent committee.

Of the 263 patients treated, 12 were enrolled in the roll-in phase and 251 were enrolled in the pivotal phase. Results are reported below principally for the 251 patients enrolled in the pivotal phase, although no significant differences in procedural success or clinical success were noted between the roll-in and pivotal cases.

Table 1, below, provides a summary of patient baseline characteristics.

Table 1. Summary of Patient Baseline Characteristics

Patient Characteristics	Aggregate
Age	
Mean + SD (n)	63.85 +/- 10.5 (251)
Range (min, max)	(35.6, 88.2)
Gender: Male	73.3% (184/251)
Current Smoker	15.1% (38/251)
Diabetes	32.3% (81/251)
History of Hypertension	72.9% (183/251)
History of Hypercholesterolemia	72.9% (183/251)
Prior MI	40.2% (101/251)
Prior CABG	16.7% (42/251)
Prior PTCA	58.6% (147/251)
Angina	84.9% (213/251)
Stable Angina	52.2% (131/251)
Unstable Angina	32.7% (82/251)
Canadian Cardiovascular Society (CCS) Angina Class III/IV*	39.0% (98/251)
Ejection Fraction: Normal (> 50%)	78.4% (192/245)
Ejection Fraction: 35-50%	20.0% (49/245)
Ejection Fraction: < 35%**	1.6% (4/245)
Pre-procedure Medication	
Asprin	94.0% (236/251)
Plavix	51.6% (129/250)
Ticlid	0.4% (1/249)

Table 2 below provides a summary of the baseline lesion characteristics.

Table 2 Baseline Lesion Characteristics*

Patient Characteristics	Aggregate	95% Confidence Interval
Reference Vessel Diameter** (mm)		
Mean + SD (n)	2.80 +/- 0.49 (319)	(2.74, 2.85)
Range (min, max)	(1.61, 4.57)	
Minimum Lumen Diameter** (mm)		
Mean + SD (n)	0.92 +/- 0.40 (320)	(0.87, 0.96)
Range (min, max)	(0.00, 2.10)	
Diameter Stenosis %		
Mean + SD (n)	67.36 +/- 12.81 (319)	(65.95, 68.77)
Range (min, max)	(29.32, 100.00)	
Lesion Length		
Mean + SD (n)	12.69 +/- 7.15 (317)	(11.90, 13.48)
Range (min, max)	(2.00, 60.28)	
Target Lesion Vessel		
RCA	29.0% (93/321)	(24.1%, 34.3%)
LAD	38.0% (122/321)	(32.7%, 43.6%)
Circumflex	31.8% (102/321)	(26.7%, 37.2%)
SVG**	1.2% (4/321)	(0.3%, 3.2%)
Calcification: Moderate/Severe	8.8% (28/320)	(5.9%, 12.4%)
Thrombus**	2.2% (7/320)	(0.9%, 4.5%)
Eccentric Lesion	28.1% (90/320)	(23.3%, 33.4%)
Angulation > 45 degrees	5.6% (18/320)	(3.4%, 8.7%)
ACC/AHA Lesion Class		
MACC Score A	11.8% (38/321)	(8.5%, 15.9%)
MACC Score B1	44.5% (143/321)	(39.0%, 50.2%)
MACC Score B2	32.4% (104/321)	(27.3%, 37.8%)
MACC Score C	0.0% (0/321)	(0.0%, 1.1%)
Total Occlusions Treated**	1.2% (4/321)	(0.3%, 3.2%)

*Baseline characteristics are reported for a total of 321 of the 349 intention-to-treat FX miniRAIL™ lesions (in 251 registry patients) for which baseline QCA was available.

**In some instances, patients who were included based on visual examination were found upon QCA to present lesions that were slightly outside the eligibility criteria, e.g., due to diameter, length, vessel type, presence of thrombus, or total occlusion. However, because eligibility was determined based on visual examination, these were not regarded as protocol deviations.

Data analysis was performed on an intent-to-treat basis. With respect to procedural success, all 251 registry patients were included in the ITT analysis, except for three patients for whom QCA data were not available to permit evaluation of residual stenosis. Among this group, the procedural success rate was 94.8% (235/248). With respect to clinical success, which required post-discharge follow-up for evaluation of non-acute MACE, the ITT analysis included the 238 patients in the registry phase of the study for whom at least a 7-day follow-up post-procedure was available. Among this group, the clinical success rate was 97.1% (231/238).

Table 3 Summary of Primary Endpoints

Effectiveness Measures	Aggregate	95% Confidence Interval
Procedural Success (In-hospital)	94.8% (235/248)	(91.2%, 97.2%)
Clinical Success	97.1% (231/238)	(94.0%, 98.8%)

Table 4 Analysis of Components of Primary Endpoints

Effectiveness Measures	Aggregate	95% Confidence Interval
Procedural Success	94.8% (235/248)	(91.2%, 97.2%)
> 50% residual diameter stenosis	2.8% (7/248)	(1.1%, 5.7%)
In-hospital Death	0.0% (0/251)	(0.0%, 1.5%)
In-hospital MI (Q wave or non-Q wave)	2.0% (5/251)	(0.7%, 4.6%)
Emergent CABG	0.4% (1/251)	(0.2%, 3.5%)
Clinical Success	97.1% (231/238)	(94.0%, 98.8%)
Death (at post-discharge follow-up)	0.0% (0/238)	(0.0%, 1.6%)
MI (at post-discharge follow-up)	2.5% (6/238)	(1.0%, 5.8%)
Q wave MI	0.8% (2/238)	(0.1%, 3.2%)
Non-Q wave MI	1.7% (4/238)	(0.5%, 4.5%)
TLR	1.3% (3/238)	(0.3%, 3.6%)

As illustrated in Table 5 below, among the 238 patients who returned for post-procedure follow-up at least 7 days post-procedure, seven experienced at least one MACE event. Six of the patients experienced the MACE event(s) while in the hospital, and one experienced a MACE event (a non Q-wave MI related to a subsequent non target lesion revascularization, not to the FX miniRAIL™ procedure) outside the hospital at 8 days post-procedure. MACE was calculated including only one event per patient. Several of these patients experienced more than one MACE event. Thus, in total, there were eleven

MACE events among the seven patients with MACE, including four non-Q wave MI, two Q-wave MI, three TLR (two PTCA and one emergent CABG), and two total occlusions.

Table 5 Combined (In-Hospital and Post-Discharge) Complications*

Event	% (N)	95% C.I.
MACE (Death, MI, TLR)	2.9% (7/238)	(1.2%, 6.0%)
Death	0.0% (0/238)	(0.0%, 1.5%)
Cardiac Death	0.0% (0/238)	(0.0%, 1.5%)
Non Cardiac Death	0.0% (0/238)	(0.0%, 1.5%)
MI	2.5% (6/238)	(0.9%, 5.4%)
Q wave MI	0.8% (2/238)	(0.1%, 3.0%)
Non-Q wave MI	1.7% (4/238)	(0.5%, 4.2%)
Target Lesion Revascularization	1.3% (3/238)	(0.3%, 3.6%)
PTCA	0.8% (2/238)	(0.1%, 3.0%)
CABG	0.4% (1/238)	(0.0%, 2.3%)
Target Vessel Revascularization	1.3% (3/238)	(0.3%, 3.6%)
PTCA	0.8% (2/238)	(0.1%, 3.0%)
CABG	0.4% (1/238)	(0.0%, 2.3%)
Total Occlusions	0.8% (2/238)	(0.1%, 3.0%)

*Because assessment of out-of-hospital events required post-discharge follow-up, these variables are reported for the 238 of 251 registry patients for whom post-discharge follow-up of at least seven days was completed.

The rate and type of dissections observed upon angiography after use of the FX miniRAIL™ was consistent with other PTCA investigations. Only two perforations were observed in the investigation, neither of which was due to the FX miniRAIL™. Additional evidence of the safety of the device is available from intravascular ultrasound (IVUS) examination of the lesions, which was performed in a subset of 55 patients at two sites. The results of this supplementary analysis also demonstrated that the type and rate of dissections were similar to other PTCA catheters. A total of twelve device failures were observed, including device malfunctions and “melon seeding” or device-related failures to cross the target lesion. There were also three failures to cross the lesion not related to the study device.

Further analysis of the data for the 77 in-stent restenosis (“ISR”) lesions treated in the study compared to the non-ISR lesions demonstrated no significant differences in either procedural success rates or clinical success rates. These results are summarized in the Table 6.

Table 6 Comparison of Outcomes in ISR versus non-ISR Lesions

	ISR	Non ISR	p value
Clinical Success	97.2% (70/72)	97.4% (148/152)	1.0000
Procedural Success	92.1% (70/76)	96.8% (153/158)	0.1829
MACE	2.8% (2/72)	2.6% (4/152)	1.0000

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In-Hospital MACE	2.6% (2/77)	1.9% (3/160)	0.6610
Out-of-Hospital MACE	0.0% (0/72)	0.7% (1/152)	1.0000
Death	0.0% (0/72)	0.0% (0/152)	N/A
MI	2.8% (2/72)	2.0% (3/152)	0.6575
Q-Wave MI	2.8% (2/72)	0.0% (0/152)	0.1023
Non Q-Wave MI	0.0% (0/72)	2.0% (3/152)	0.5529
TLR	1.4% (1/72)	0.7% (1/152)	0.5405
Total Occlusions at 14 days	1.4% (1/72)	0.0% (0/152)	0.3124
Acute Stent Thrombosis (to 24 hours)	0.0% (0/77)	0.0% (0/160)	N/A

MATERIALS REQUIRED FOR USE WITH THE FX miniRAIL™ RX PTCA CATHETER:

WARNING: Use single use items only. Do not resterilize or reuse.

- Femoral or brachial guiding catheter in the appropriate size and configuration to select the coronary artery
- Hemostatic valve(s)
- Contrast medium diluted 1:1 with normal saline
- Sterile heparinized normal saline
- Syringe for saline flushing of the dilatation catheter's guide wire lumen
- Inflation device with manometer
- Appropriately sized guide wire (0.014 in. maximum allowable diameter)
- Guide wire introducer
- Guide wire torque device
- 20cc Luer-lock syringe (optional)

INSTRUCTIONS FOR USE

Prior to use of the dilatation catheter in PTCA, all equipment to be used for the procedure, including the dilatation catheter, should be examined carefully for defects. Examine the dilatation catheter for bends, kinks, or other damage. Do not use any defective equipment. Prepare equipment to be used following the manufacturer's instructions or standard practice.

PREPARATION OF THE FX miniRAIL™ RX PTCA CATHETER

1. Using sterile technique, remove the FX miniRAIL™ RX PTCA Catheter and protective hoop dispenser from the sterile pouch and place on the sterile field.
2. Slide the dilatation catheter out of the hoop dispenser.
3. Grasp the balloon protector sleeve at its proximal end and carefully slide it off the balloon section.
4. Gently flush the guide wire lumen with sterile, heparinized saline solution (the solution will exit at the distal end of the balloon).
5. Prepare the inflation device with the recommended contrast medium, according to the manufacturer's instructions.
6. To withdraw air from the balloon segment, the following steps should be taken:
 - a. Fill the 20cc syringe or the inflation device with approximately 4cc of the recommended contrast medium.
 - b. After attaching the syringe or inflation device to the dilatation catheter's proximal balloon inflation lumen, orient the catheter with the distal tip and its balloon into a downward vertical position.
 - c. Apply negative pressure and aspirate for 20 seconds. Slowly release the pressure to neutral, allowing contrast to fill the shaft of the dilatation catheter.

- d. Disconnect the syringe or inflation device from the inflation port of the dilatation catheter.
 - e. Remove all air from the syringe or inflation device barrel. Reconnect the syringe or inflation device to the inflation port of the dilatation catheter. Maintain negative pressure on the balloon until air no longer returns to the device.
 - f. Slowly release the inflation device pressure to neutral.
7. Disconnect the 20cc syringe (if used) and connect the inflation device to the inflation port of the dilatation catheter without introducing air into the system.
- NOTE: All air must be removed from the balloon and displaced with contrast medium prior to inserting into the body (repeat steps 6a through 6f, if necessary).**

USE OF THE FX miniRAIL™ RX PTCA CATHETER

1. Introduce the guiding catheter using the manufacturer's guidelines or standard technique. The choice of guiding catheter depends on patient anatomy and lesion location.
2. Insert the guide wire through the hemostatic valve on the guiding catheter, following the manufacturer's guidelines or standard practice. Advance the guide wire carefully into and through the guiding catheter. When complete, withdraw the guide wire introducer, if used.
3. Attach the torque device to the wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel and then across the stenosis.
4. Backload the distal tip of the dilatation catheter onto the proximal end of the guide wire, ensuring that the guide wire exits the notch located distally to the balloon. Advance the dilatation catheter over the guide wire by grasping only the black hypotube shaft. As the tip approaches the hemostatic valve, loosen the knurled knob on the valve. Insert the dilatation catheter while maintaining guide wire position and retighten the knurled knob. To facilitate insertion, the balloon must be fully deflated to negative pressure.

NOTE: When backloading the catheter onto the guide wire, the catheter should be supported, ensuring that the guide wire does not come in contact with the balloon.

5. Tighten the knurled knob to create a seal around the dilatation catheter without preventing movement of the catheter. This will allow continuous recording of proximal coronary artery pressure.

NOTE: It is important that the hemostatic valve be closed tightly enough to prevent blood leakage around the catheter shaft, yet not so tight that it restricts the flow of contrast into and out of the balloon or restricts guide wire movement.

6. Grasp only the black hypotube shaft and advance the dilatation catheter until the appropriate proximal marker is visible at the guiding catheter's tip.
7. Continue to advance the dilatation catheter over the guide wire and into the stenosis under fluoroscopy. Inflate the balloon to a very low pressure (1 atm, 1 bar, or 15 psi) to confirm that the balloon is correctly positioned.
8. X Technologies recommends the following balloon inflation protocol which was used in the clinical study:
 - a. Begin inflation at 2 atm, and remain at this pressure for 20 seconds.
 - b. Increase inflation pressure in a step-up procedure at a rate of 1 atm every 20 seconds until the indentation in the balloon disappears (this pressure is the "Stenosis Resolution Pressure" or SRP). Hold at the SRP for 10 seconds.
 - c. After SRP is achieved, increase inflation pressure at a rate of 1 atm every

10 seconds until the target balloon diameter is achieved by fluoroscopic assessment. Hold at the final (maximum) pressure for 20 seconds.

d. If the continuous balloon inflation in the above steps results in patient discomfort or ST segment changes, the physician may modify the inflation protocol as follows:

Deflate the balloon and allow the ischemia to resolve.

Resume the inflation protocol, starting at the highest pressure achieved during the previous inflation. **Use a rate of 1 atm / 2 sec to inflate the balloon from zero to the new starting pressure.**

e. After the target balloon diameter is achieved, additional inflations may be performed at the discretion of the physician. Additional inflations are to be performed at a rate of 1 atm/2 sec. Maintain negative pressure on the balloon between inflations.

9. To remove the dilatation catheter, apply negative pressure to the inflation device and confirm that the balloon is fully deflated. The catheter should be retracted only by grasping the black hypotube shaft.

10. Withdraw the deflated dilatation catheter through the hemostatic valve. If insertion of another catheter is desired, the guide wire may be kept in place.

11. Tighten the knurled knob on the hemostatic valve.

Balloon Compliance and Rated Burst Pressure:

Balloon Compliance for FX miniRAIL™ Catheters – 10, 15, 20 & 30mm Lengths									
FX20XX		FX25XX		FX30XX		FX35XX		FX40XX	
PRESSURE (ATM)	DIAMETER (mm)	PRESSURE (ATM)	DIAMETER (mm)	PRESSURE (ATM)	DIAMETER (mm)	PRESSURE (ATM)	DIAMETER (mm)	PRESSURE (ATM)	DIAMETER (mm)
2.0	1.62	2.0	2.13	2.0	2.50	2.0	2.85	2.0	3.39
4.0	1.76	4.0	2.32	4.0	2.67	4.0	3.07	4.0	3.70
6.0	1.87	6.0	2.49	6.0	2.83	6.0	3.29	6.0**	3.99
8.0**	1.96	8.0**	2.62	8.0**	2.98	8.0**	3.50	8.0	4.21
10.0	2.04	10.0	2.73	10.0	3.10	10.0	3.68	10.0	4.39
12.0	2.10	12.0	2.84	12.0	3.20	12.0	3.83	12.0*	4.57
14.0*	2.15	13.0*	2.89	13.0*	3.25	13.0*	3.90		

** NOMINAL DIAMETER

* RATED BURST PRESSURE

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